K042227

NOV 19 2004

510(k) Summary of

Safety and Effectiveness as Required by 21 CFR 807.92

Manufacture and Submitter	**Name:**	Alfa Scientific Designs, Inc.
	Address:	12330 Stowe Drive Poway, CA 92064 Telephone: (858) 513-3888 x 308 Fax: (858) 513-8388
	Contact Person:	Naishu Wang, MD, Ph.D.
	E-mail:	wnss@alfascientific.com
Device Name	**Trade Name:**	*INSTANT-VIEW®* Troponin I Serum Cassette Test *INSTANT-VIEW®* Troponin I Serum Dip Strip Test *INSTANT-VIEW®* Troponin I Whole Blood/Serum Test
	Common Name:	Immunoassay, Troponin I Test
	Classification:	Creatine phosphokinase/creatine kinase or isoenzymes test system
Date of Summary Preparation	August 12, 2004	
Predicate Device	VBL Serum Troponin I Test by Vancouver Biotech LTD. K023505	
Device Description	A one-step lateral flow chromatographic immunoassay. The test strip in the device consists of 1) a burgundy-colored conjugate pad containing colloidal gold coupled with anti- Troponin I antibodies, and 2) nitrocellulose membrane containing a test line (T line) and a control line (C line). The T line is coated with anti- Troponin I antibodies, and the C line is coated with goat anti-mouse IgG antibodies.	
Summary of the Similarity to the Predicate Device	• Both are one-step lateral-flow chromatographic immunoassays. • Both are qualitative tests. • Both are in-vitro diagnostic devices. • Both have a built-in quality control feature, C line, to indicate that an adequate volume of sample is applied and the liquid flow occurred properly	

Intended Use	The *INSTANT-VIEW®* Troponin I Test is an immunoassay for the rapid qualitative detection of cardiac troponin I (cTnI) in human whole blood or serum at a cutoff level of 1.5 ng/ml. It provides an aid in the diagnosis of myocardial infarction in emergency room, point-of-care, and hospital setting.
Sensitivity and Specificity Study	The sensitivity and specificity of the device was evaluated against 300 clinically confirmed serum specimens, 150 positive and 150 negative. The results demonstrated that the *INSTANT-VIEW®* Troponin I Test have a sensitivity of 99.3% (149/150) and a specificity of 96.0% (144/150). The overall accuracy of this device is 97.7% (293/300).
Reproducibility study	Reproducibility studies were performed on 80 samples with the concentration of human cardiac troponin I evenly distributed at four different levels: 0, 0.1, 1.5, 10 ng/ml. Each sample was tested at three physician's office laboratories (POLs) and one medical analysis laboratory. The agreements at the four sites were over 98.8%.
Interference and Cross-reactivity Study	No cross-reaction was observed with the closely related substances, such as troponins other than human cardiac troponin bilirubin, and cholesterols. No interference was observed with endogenous substances including commonly used drugs or analytes at a concentration of 10 μg/ml.
Formats of the Device	The proposed device has two formats: Serum Test and Whole Blood/Serum Test. The Serum Test has two sub-formats: Cassette and Dip Strip. The Whole Blood/Serum Test only has the cassette format. A cassette is a device that assembles a dip-strip in a plastic housing. The studies demonstrate all the formats are equivalent.
Conclusion	The results of specificity, sensitivity, reproducibility, cross reactivity, and interference studies demonstrate that the *INSTANT-VIEW®* Troponin I Test is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 19 2004

Naishu Wang, MD., Ph.D.
President
Alfa Scientific Designs, Inc.
12330 Stowe Drive
Poway, CA 92064

Re: k042227
Trade/Device Name: *INSTANT-VIEW®* Troponin I Serum Test (Cassette)
INSTANT-VIEW® Troponin I Serum Test (Dip Strip)
INSTANT-VIEW® Troponin I Whole Blood/Serum Test (Cassette)
Regulation Number: 21 CFR 862.1215
Regulation Name: Creatine phosphokinase/creatine kinase or isoenzymes test system
Regulatory Class: Class II
Product Code: MMI
Dated: October 28, 2004
Received: November 4, 2004

Dear Dr. Wang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Cornelia B. Rooks

Cornelia B. Rooks, MA
Acting Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K042227

Device Name: *INSTANT-VIEW®* Troponin I Serum Test (Cassette)
INSTANT-VIEW® Troponin I Serum Test (Dip Strip)
INSTANT-VIEW® Troponin I Whole Blood/Serum Test (Cassette)

Indications For Use:

The *INSTANT-VIEW®* Troponin I Test is an immunoassay for the rapid qualitative detection of cardiac troponin I (cTnI) in human whole blood or serum at a cutoff level of 1.5 ng/ml. It provides an aid in the diagnosis of myocardial infarction in emergency room, point-of-care, and hospital setting.

The INSTANT-VIEW® Troponin I Test provides a qualitative result rather than information about change in the level of cTnI with single testing. Serial testing should be performed to determine a temporal change in the level of cTnI. If desired, a quantitative method should be used to quantitate the concentration of cTnI. Clinical consideration and professional judgment should be applied when making a diagnosis decision based on this test result.

Prescription Use ✓ AND/OR Over-The-Counter Use_____
(Pert 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol Benson
Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

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